

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE:

17-MD-2767 (PAE)

17-MC-2767 (PAE)

MIRENA IUS LEVONORGESTREL-  
RELATED PRODUCTS LIABILITY  
LITIGATION (NO. II)

*This Document Relates To All Actions*

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**DEFENDANTS' ORIGINAL GLOBAL ANSWER  
TO PLAINTIFFS' CONSOLIDATED AMENDED COMPLAINT**

Defendants Bayer HealthCare Pharmaceuticals Inc. ("BHCP"), Bayer Pharma AG, and Bayer Oy, by and through their undersigned counsel, hereby answer Plaintiffs' Consolidated Amended Complaint (the "Complaint"). Defendants specifically deny each and every allegation of the Complaint not otherwise expressly admitted, qualified, or denied in this Answer. BHCP states that it is answering Plaintiffs' allegations only on behalf of itself, unless the term "Defendants" is used, even where Plaintiffs' allegations refer to alleged conduct by other entities. Bayer Pharma AG states that it is answering Plaintiffs' allegations only on behalf of itself, unless the term "Defendants" is used, even where Plaintiffs' allegations refer to alleged conduct by other entities. Bayer Oy states that it is answering Plaintiffs' allegations only on behalf of itself, unless the term "Defendants" is used, even where Plaintiffs' allegations refer to alleged conduct by other entities. Defendants deny the allegations in the last sentence of the second of the Complaint's introductory paragraphs, as well as the allegations in the third of the Complaint's introductory paragraphs.

**FIRST RESPONSE TO “PARTIES”**

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint.

2. BHCP admits that it is a Delaware corporation with its principal place of business located at 100 Bayer Boulevard, Whippany, New Jersey 07981 and that it is a citizen of Delaware and New Jersey. The allegations in Paragraph 2 of the Complaint are directed at a defendant other than Bayer Pharma AG and Bayer Oy, and therefore, no response is required for those entities.

3. Bayer Pharma AG admits that it is organized under the laws of Germany and that it is a citizen of Germany. Bayer Pharma AG denies any remaining allegations in Paragraph 3 of the Complaint. The allegations in Paragraph 3 of the Complaint are directed at a defendant other than BHCP and Bayer Oy, and therefore, no response is required for those entities.

4. Bayer Pharma AG denies the allegations in Paragraph 4 of the Complaint. The allegations in Paragraph 4 of the Complaint are directed at a defendant other than BHCP and Bayer Oy, and therefore, no response is required for those entities.

5. Bayer Pharma AG denies the allegations in Paragraph 5 of the Complaint. The allegations in Paragraph 5 of the Complaint are directed at a defendant other than BHCP and Bayer Oy, and therefore, no response is required for those entities.

6. Paragraph 6 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Bayer Pharma AG denies the allegations in Paragraph 6 of the Complaint. The allegations in Paragraph 6 of the Complaint are directed at a defendant other than BHCP and Bayer Oy, and therefore, no response is required for those entities.

7. Bayer Oy admits that it is a Finnish corporation with its principal place of business located at Pansiontie 47, Turku, Varsinais-Suomi, 20210 Finland and that it is a citizen of Finland. The allegations in Paragraph 7 of the Complaint are directed at a defendant other than BHCP and Bayer Pharma AG, and therefore, no response is required for those entities.

8. Bayer Oy admits that it is the owner of the Mirena<sup>®</sup> trademark in the United States. The allegations in Paragraph 8 of the Complaint are directed at a defendant other than BHCP and Bayer Pharma AG, and therefore, no response is required for those entities.

9. Bayer Oy denies the allegations contained in Paragraph 9. The allegations in Paragraph 9 of the Complaint are directed at a defendant other than BHCP and Bayer Pharma AG, and therefore, no response is required for those entities.

10. Bayer Oy denies the allegations contained in Paragraph 10. The allegations in Paragraph 10 of the Complaint are directed at a defendant other than BHCP and Bayer Pharma AG, and therefore, no response is required for those entities.

11. BHCP admits that it was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc. Defendants Bayer Pharma AG and Bayer Oy deny that they were formerly known as Berlex, Inc. or Berlex Laboratories, Inc.

12. The allegations contained in Paragraph 12 are denied as stated. BHCP admits that it was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc. The remaining allegations contained in Paragraph 12 are denied.

13. Defendants deny that Bayer Pharmaceuticals, Inc. is the holder of the approved New Drug Application (“NDA”) for Mirena<sup>®</sup>. Defendants admit that BHCP is the holder of the approved NDA for Mirena<sup>®</sup>.

14. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, advertised, promoted, marketed, sold, and distributed Mirena<sup>®</sup> as an intrauterine contraceptive system (“IUS”) in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 14, BHCP is without knowledge or information sufficient to form a belief as to the truth of those. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup>. Bayer Pharma AG further admits that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it manufactured Mirena<sup>®</sup>, and also denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 14, Bayer Pharma AG is without knowledge or information sufficient to form a belief as to the truth of those. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 14, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those.

15. BHCP admits that, at certain times not specifically set forth in the Complaint, it advertised, promoted, marketed and sold Mirena<sup>®</sup> and other prescription drugs in all fifty States in the United States. Bayer Pharma AG and Bayer Oy deny the allegations in Paragraph 15 of the Complaint.

16. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, marketed, distributed, and/or sold Mirena<sup>®</sup> in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 16, BHCP is without knowledge or information sufficient to form a belief as to the truth of those. BHCP denies the remaining allegations in Paragraph 16. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup> and granted BHCP a license to market the product in the United States. Bayer Pharma AG further admits that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it manufactured Mirena<sup>®</sup>, and also denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 16, Bayer Pharma AG is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the remaining allegations in Paragraph 16 of the Complaint. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>, and licensed the product to BHCP. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 16, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the remaining allegations in Paragraph 16 of the Complaint.

**FIRST RESPONSE TO “JURISDICTION AND VENUE”**

17. Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP admits that it is subject to general jurisdiction in

Delaware and New Jersey State Courts. Defendants deny the remaining allegations in Paragraph 17 of the Complaint.

18. Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in Paragraph 18 of the Complaint.

19. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19, and therefore, deny the allegations in Paragraph 20 of the Complaint.

20. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20, and therefore, deny the allegations in Paragraph 20 of the Complaint.

#### **FIRST RESPONSE TO “FACTS”**

21. Defendants admit that Mirena<sup>®</sup> is an IUS made of soft, flexible plastic, that it consists of a T-shaped polyethylene frame (T-body) with a steroid reservoir (hormone elastomer core) around the vertical stem, that it requires a prescription, and that it is put in place by a healthcare provider during an office visit. Defendants also admit that Mirena<sup>®</sup> contains 52 mg of levonorgestrel, which is released at an initial rate of approximately 20 mcg/day. This rate decreases progressively to half that value after five years. Defendants deny the remaining allegations in Paragraph 21 of the Complaint.

22. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, promoted, marketed, distributed, and/or sold Mirena<sup>®</sup>. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup> and granted BHCP a license to market the product in the United States. Bayer Pharma AG further admits

that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it manufactured Mirena<sup>®</sup>, and also denies that it marketed, advertised, promoted, or sold Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 22, BHCP is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, BHCP denies the remaining allegations in Paragraph 22 of the Complaint. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 22, Bayer Pharma AG is without knowledge or information sufficient to form a belief as to the truth of those, and therefore denies the remaining allegations in Paragraph 22 of the Complaint. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>, and licensed the product to BHCP. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, advertised, promoted or sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 22, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the remaining allegations in Paragraph 22 of the Complaint.

23. Defendants admit that the FDA approved Berlex Laboratories Inc.'s new drug application for Mirena<sup>®</sup> in December 2000.

24. Defendants admit that in 2009 the FDA approved Mirena<sup>®</sup> as a treatment indicated for heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception.

25. Defendants admit the allegations in Paragraph 25 of the Complaint.

26. Defendants admit the allegations in Paragraph 26 of the Complaint.

27. Defendants admit that the allegations in Paragraph 27 purport to selectively quote, paraphrase, and/or reference the FDA-approved Patient Information Booklet and Prescribing Information, which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

28. Defendants admit that the allegations in Paragraph 28 purport to selectively quote, paraphrase, and/or reference the FDA-approved Physician Prescribing Information for Mirena<sup>®</sup> and the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

29. Defendants admit that the allegations in Paragraph 29 purport to selectively quote, paraphrase, and/or reference the FDA-approved label for Mirena<sup>®</sup>, but deny that the FDA-approved Mirena<sup>®</sup> label is quoted, paraphrased, and/or referenced in context or in its entirety. Defendants state that the FDA-approved label for Mirena<sup>®</sup> speaks for itself, and to the extent that Plaintiffs' allegations are inconsistent with the actual language or content of the FDA-approved label for Mirena<sup>®</sup>, Defendants deny those allegations.

30. Defendants admit that the allegations in Paragraph 30 purport to selectively quote, paraphrase, and/or reference the FDA-approved Patient Information Booklet, Physician Prescribing Information, and other vaguely referenced "labeling, brochures, publications, or advertisements," which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with the actual language or content of the documents,



Defendants deny those allegations. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and pseudotumor cerebri (“PTC”) or Mirena<sup>®</sup> and idiopathic intracranial hypertension (“IIH”) and therefore, the FDA-approved label for Mirena<sup>®</sup> and Mirena<sup>®</sup> brochures, publications and advertisements do not specifically warn about those conditions.

31. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants deny the remaining allegations in Paragraph 31 of the Complaint.

32. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants deny the remaining allegations in Paragraph 32 of the Complaint.

33. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 33, and therefore, deny the remaining allegations in Paragraph 33 of the Complaint.

34. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 34, and therefore, deny the remaining allegations in Paragraph 34 of the Complaint.

35. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants further admit that that there is no evidence that Mirena<sup>®</sup> can cause PTC/IIH, and therefore Defendants have not informed anyone that Mirena<sup>®</sup> can cause PTC/IIH. Defendants deny any remaining allegations in Paragraph 35 of the Complaint.

36. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants further admit that that there is no evidence that Mirena<sup>®</sup> can cause PTC/IIH, and therefore Defendants have not informed anyone that Mirena<sup>®</sup> can cause PTC/IIH. Defendants deny any remaining allegations in Paragraph 36 of the Complaint.

37. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants further admit that that there is no evidence that Mirena<sup>®</sup> can cause PTC/IIH, and therefore Defendants have not informed anyone that Mirena<sup>®</sup> can cause PTC/IIH. Defendants deny any remaining allegations in Paragraph 37 of the Complaint.

38. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants further admit that that there is no evidence that Mirena<sup>®</sup> can increase the risk of PTC/IIH, and therefore

Defendants have not informed anyone that Mirena<sup>®</sup> can increase the risk of PTC/IIH. Defendants deny any remaining allegations in Paragraph 38 of the Complaint.

39. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants further admit that that there is no evidence that Mirena<sup>®</sup> can increase the risk of PTC/IIH, and therefore Defendants have not informed anyone that Mirena<sup>®</sup> can increase the risk of PTC/IIH. Defendants deny any remaining allegations in Paragraph 39 of the Complaint.

40. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants further admit that that there is no evidence that Mirena<sup>®</sup> can increase the risk of PTC/IIH, and therefore Defendants have not informed anyone that Mirena<sup>®</sup> can increase the risk of PTC/IIH. Defendants deny any remaining allegations in Paragraph 40 of the Complaint.

41. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants further admit that that there is no evidence that Mirena<sup>®</sup> can increase the risk of PTC/IIH, and therefore Defendants have not informed anyone that Mirena<sup>®</sup> can increase the risk of PTC/IIH. Defendants deny any remaining allegations in Paragraph 41 of the Complaint.

42. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH, and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants further admit

that that there is no evidence that Mirena<sup>®</sup> can increase the risk of PTC/IIH, and therefore Defendants have not informed anyone that Mirena<sup>®</sup> can increase the risk of PTC/IIH. Defendants deny any remaining allegations in Paragraph 42 of the Complaint.

43. Defendants admit that there is no scientifically reliable evidence of a causal relationship between Mirena<sup>®</sup> and PTC or Mirena<sup>®</sup> and IIH, and therefore, the FDA-approved label for Mirena<sup>®</sup> does not specifically warn about those conditions. Defendants further admit that that there is no evidence that Mirena<sup>®</sup> can increase the risk of PTC/IIH, and therefore Defendants have not informed anyone that Mirena<sup>®</sup> can increase the risk of PTC/IIH. Defendants deny any remaining allegations in Paragraph 43 of the Complaint.

44. Defendants deny that it is well established in the medical and scientific communities that Mirena<sup>®</sup> can cause PTC/IIH, and deny that it is well established in the medical and scientific communities that there is confirmed evidence for a causal association of levonorgestrel implant use and PTC/IIH. Defendants admit that it is proposed that some medications may be possible risk factors for intracranial hypertension; however, studies of medications associated with intracranial hypertension are mostly uncontrolled and retrospective. Accordingly, Defendants deny the allegations in Paragraph 44 of the Complaint.

45. Defendants deny the allegations in Paragraph 45 of the Complaint.

46. Defendants admit that, based on data from the 1980s, the annual incidence rate for PTC/IIH has been cited as around 1 per 100,000 in the US population generally, and admit that when confined to women aged 20–44 years, who are 20% or more above their ideal bodyweight, those same data yielded an incidence of approximately 19 cases per 100,000 in the United States population. Defendants deny any remaining allegations in Paragraph 46 of the Complaint.

47. Paragraph 47 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny that they have not provided Plaintiffs the clinical trial data regarding levonorgestrel that the MDL Court, after written and oral argument, ordered Defendants to produce.

48. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48 of the Complaint.

49. Defendants deny the allegations in Paragraph 49 of the Complaint.

50. Defendants deny the allegations in Paragraph 50 of the Complaint.

51. Defendants deny the allegations in Paragraph 51 of the Complaint.

52. Defendants deny the allegations in Paragraph 52 of the Complaint.

53. Defendants deny the allegations in Paragraph 53 of the Complaint.

54. Defendants admit that the allegations in Paragraph 54 purport to selectively quote, paraphrase, and/or reference Defendants' analysis, which document being in writing, speaks for itself. Defendants deny that Plaintiff's allegations are consistent with the actual language or context of the document, and therefore, Defendants deny the allegations in Paragraph 54 of the Complaint.

55. Defendants deny the allegations in Paragraph 55 of the Complaint.

56. Defendants admit that the article referenced in Paragraph 56 was published by the referenced journal. Defendants further admit that the allegations in Paragraph 56 purport to selectively quote, paraphrase, and/or reference Defendants' analysis, which document being in writing, speaks for itself. Defendants deny that Plaintiff's allegations are consistent with the actual language or context of the document, and therefore, Defendants deny the allegations in Paragraph 56 of the Complaint.

57. Defendants deny the allegations in Paragraph 57 of the Complaint.

**FIRST RESPONSE TO “PSEUDOTUMOR CEREBRI ALSO KNOWN AS IDIOPATHIC  
INTRACRANIAL HYPERTENSION”**

58. Defendants admit that IIH is also termed pseudotumor cerebri and benign intracranial hypertension and is the clinical syndrome of raised intracranial pressure, in the absence of space-occupying lesions or vascular lesions, without enlargement of the cerebral ventricles, for which no causative factor can be identified.

59. Defendants admit the allegations in Paragraph 59 of the Complaint.

60. Defendants admit that patients with PTC or IIH typically develop papilledema, or optic disc swelling due to increased intracranial pressure. Defendants deny any remaining allegations in Paragraph 60 of the Complaint.

61. Defendants admit that the most common symptom for PTC/IIH is headache. Defendants also admit that patients can have transient visual obscurations, blurred vision, photophobia and/or double vision. Defendants deny the remaining allegations in Paragraph 61 of the Complaint.

62. Defendants deny the allegations in Paragraph 62 of the Complaint.

63. Defendants deny the allegations in Paragraph 63 of the Complaint.

64. Defendants admit the allegations as stated in Paragraph 64 of the Complaint; however, Defendants deny that permanent vision loss or blindness is a common occurrence with PTC/IIH.

65. Defendants deny the allegations in Paragraph 65 of the Complaint.

66. Defendants admit that PTC/IIH patients can have recurrences. Defendants deny any remaining allegations in Paragraph 66 of the Complaint.

67. Defendants admit the allegations in the first sentence of Paragraph 67 of the Complaint. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 67, Defendants are without knowledge or information sufficient to form a belief as to the truth of those, and therefore, deny the same.

68. Defendants admit that cerebrospinal fluid shunts are occasionally used to treat severe IIH refractory to medical management. Defendants deny the remaining allegations in Paragraph 68 of the Complaint.

69. Defendants admit that a lumboperitoneal (“LP”) shunt is a kind of shunt occasionally used to treat IIH. Defendants deny the remaining allegations in Paragraph 69 of the Complaint.

70. Defendants admit that a ventriculoperitoneal (“VP”) shunt is a kind of shunt occasionally used to treat IIH. Defendants deny the remaining allegations in Paragraph 70 of the Complaint.

71. Defendants deny the allegations in Paragraph 71 of the Complaint.

72. Defendants deny the allegations in Paragraph 72 of the Complaint.

73. Defendants admit that stenting procedures are occasionally used to treat severe IIH refractory to medical management. Defendants deny the remaining allegations in Paragraph 73 of the Complaint.

**FIRST RESPONSE TO “THE HORMONE IN MIRENA:**

**LEVONORGESTREL OR ‘LNG’”**

74. Defendants admit the allegations in Paragraph 74 of the Complaint but state that the Plaintiff misspelled “progestagens” as “protestagens.”

75. Defendants deny the allegations in Paragraph 75 of the Complaint.

76. Defendants deny the allegations in Paragraph 76 of the Complaint.
77. Defendants deny the allegations in Paragraph 77 of the Complaint.
78. Defendants deny the allegations in Paragraph 78 of the Complaint.
79. Defendants deny the allegations in Paragraph 79 of the Complaint.
80. Defendants deny the allegations in Paragraph 80 of the Complaint.
81. Defendants deny the allegations in Paragraph 81 of the Complaint.
82. Defendants deny the allegations in Paragraph 82 of the Complaint.
83. Defendants deny the allegations in Paragraph 83 of the Complaint.
84. Defendants deny the allegations in Paragraph 84 of the Complaint.
85. Defendants deny the allegations in Paragraph 85 of the Complaint.
86. Defendants deny the allegations in Paragraph 86 of the Complaint.
87. Defendants deny the allegations in Paragraph 87 of the Complaint.
88. Defendants deny the allegations in Paragraph 88 of the Complaint.
89. Defendants deny the allegations in Paragraph 89 of the Complaint.
90. Defendants deny the allegation s in Paragraph 90 of the Complaint.
91. Defendants deny the allegations in Paragraph 91 of the Complaint.
92. Defendants deny the allegations in Paragraph 92 of the Complaint.
93. Defendants deny the allegations in Paragraph 93 of the Complaint.
94. Defendants admit the allegations in Paragraph 94 of the Complaint.
95. Defendants admit that total serum LNG levels are higher with EE, but deny the remaining allegations in Paragraph 95 of the Complaint.
96. Defendants deny the allegations in Paragraph 96 of the Complaint.
97. Defendants deny the allegations in Paragraph 97 of the Complaint.



98. Defendants deny the allegations in Paragraph 98 of the Complaint.

99. Defendants deny the allegations in Paragraph 99 of the Complaint.

100. Defendants deny the allegations in Paragraph 100 of the Complaint.

101. Defendants deny the allegations in Paragraph 101 of the Complaint.

102. Defendants deny the allegations in Paragraph 102 of the Complaint.

103. Defendants admit that the allegations in Paragraph 103 purport to selectively quote, paraphrase, and/or reference the FDA-approved Physician Prescribing Information for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations.

104. Defendants admit the allegations in Paragraph 104 of the Complaint.

105. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 105 of the Complaint, and therefore, deny the same.

106. Defendants admit the allegations in Paragraph 106 of the Complaint.

107. Defendants admit the allegations in Paragraph 107 of the Complaint.

108. Defendants deny the allegations in Paragraph 108 of the Complaint.

109. Defendants deny the allegations in Paragraph 109 of the Complaint.

110. Defendants deny the allegations in Paragraph 110 of the Complaint.

111. Defendants deny the allegations in Paragraph 111 of the Complaint.

**FIRST RESPONSE TO "DEFENDANTS' REPRESENTATIONS**

**REGARDING MIRENA AND LNG"**

112. Defendants answer that, to the extent the allegations in Paragraph 112 purport to selectively quote, paraphrase, and/or reference the FDA-approved Physician Prescribing

Information, that document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with the actual language or content of the document, Defendants deny those allegations.

113. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 113 of the Complaint.

114. Defendants answer that, to the extent the allegations in Paragraph 114 purport to selectively quote, paraphrase, and/or reference the FDA-approved label for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent Plaintiff's allegations are inconsistent with, or take out of context, the entirety of the Mirena<sup>®</sup> label, Defendants deny those allegations.

115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 115 of the Complaint.

116. Defendants admit that the allegations in Paragraph 116 purport to selectively quote, paraphrase, and/or reference the FDA-approved label for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with the actual language or content of the document, Defendants deny those allegations.

117. Defendants deny the allegations in Paragraph 117 of the Complaint.

118. Defendants deny the allegations in Paragraph 118 of the Complaint.

119. Defendants admit that the allegations in Paragraph 119 purport to selectively quote, paraphrase, and/or reference the FDA-approved label, patient education and marketing materials for Mirena<sup>®</sup>, which documents, being in writing speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

120. Defendants admit that the allegations in Paragraph 120 purport to selectively quote, paraphrase, and/or reference the FDA-approved label, patient education and marketing materials for Mirena<sup>®</sup>, which documents, being in writing speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

121. Defendants deny the allegations in Paragraph 121 of the Complaint.

122. Defendants answer that, to the extent the allegations in Paragraph 122 purport to selectively quote, paraphrase, and/or reference the FDA-approved label for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with the actual language or content of the document, Defendants deny those allegations.

123. Defendants answer that, to the extent the allegations in Paragraph 123 purport to selectively quote, paraphrase, and/or reference the FDA-approved label for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with the actual language or content of the document, Defendants deny those allegations.

124. Defendants admit that the allegations in Paragraph 124 (and its subparts) purport to selectively quote, paraphrase, and/or reference the FDA-approved Physician Prescribing Information for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations.

125. Defendants admit that the allegations in Paragraph 125 purport to selectively quote, paraphrase, and/or reference the FDA-approved label, patient education and marketing

materials for Mirena<sup>®</sup>, which documents, being in writing speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

126. Defendants admit that the allegations in Paragraph 126 purport to selectively quote, paraphrase, and/or reference the FDA-approved label for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations.

127. Defendants admit that the allegations in Paragraph 127 purport to selectively quote, paraphrase, and/or reference the FDA-approved label for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations.

128. Defendants admit that the allegations in Paragraph 128 purport to selectively quote, paraphrase, and/or reference the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations.

129. Defendants admit that the allegations in Paragraph 129 purport to selectively quote, paraphrase, and/or reference the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations.

130. Defendants admit that the allegations in Paragraph 130 purport to selectively quote, paraphrase, and/or reference the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations.

131. Defendants admit that the allegations in Paragraph 131 purport to selectively quote, paraphrase, and/or reference the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations.

132. Defendants admit that the allegations in Paragraph 132 purport to selectively quote, paraphrase, and/or reference the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations.

133. Defendants deny the allegations in Paragraph 133 of the Complaint.

134. BHCP admits that, at certain times not specifically set forth in the Complaint, it advertised, promoted, marketed, and sold Mirena<sup>®</sup> as an IUS. Bayer Pharma AG denies that it marketed Mirena<sup>®</sup> to patients or consumers in the United States. Bayer Oy denies that it marketed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 134, Defendants are without knowledge or information sufficient to form a belief as to the truth of those, and therefore, deny the same.

135. Defendants deny the allegations in Paragraph 135 of the Complaint.

136. BHCP admits that, at certain times not specifically set forth in the Complaint, it used sales representatives and key opinion leaders to market Mirena<sup>®</sup> as an IUS. Bayer Pharma AG denies that it marketed Mirena<sup>®</sup> to patients or consumers in the United States. Bayer Oy denies that it marketed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 136, Defendants are without knowledge or information sufficient to form a belief as to the truth of those.

137. Defendants deny the allegations in Paragraph 137 of the Complaint.

138. Defendants admit that the allegations in Paragraph 138 purport to selectively quote, paraphrase, and/or reference the FDA-approved label and/or marketing materials for Mirena<sup>®</sup>, which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

139. Defendants admit that the allegations in Paragraph 139 purport to selectively quote, paraphrase, and/or reference the FDA-approved label, patient education and/or marketing materials for Mirena<sup>®</sup>, which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

140. Defendants admit that the allegations in Paragraph 140 purport to selectively quote, paraphrase, and/or reference the Mirena<sup>®</sup> website, which, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of the Mirena<sup>®</sup> website, Defendants deny those allegations.

141. Defendants admit that the allegations in Paragraph 141 purport to selectively quote, paraphrase, and/or reference the Mirena<sup>®</sup> website, which, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of the Mirena<sup>®</sup> website, Defendants deny those allegations.

142. Defendants admit that the allegations in Paragraph 142 purport to selectively quote, paraphrase, and/or reference the FDA-approved Physician Prescribing Information for Mirena<sup>®</sup> and the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

143. Defendants admit that the allegations in Paragraph 143 (and its subparts) purport to selectively quote, paraphrase, and/or reference the FDA-approved Physician Prescribing Information for Mirena<sup>®</sup> and the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

144. Defendants deny the allegations in Paragraph 144 of the Complaint.

145. Defendants deny the allegations in Paragraph 145 of the Complaint.

146. Defendants deny the allegations in Paragraph 146 of the Complaint.

147. Defendants deny the allegations in Paragraph 147 of the Complaint.

148. Paragraph 148 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

**FIRST RESPONSE TO “NORPLANT® AND OTHER LONG-TERM LNG-RELEASING  
CONTRACEPTIVES WARN OF PTC/IIIH”**

149. Defendants admit the allegations in Paragraph 149 of the Complaint.

150. Defendants admit the allegations in Paragraph 150 of the Complaint.

151. Defendants admit the allegations in Paragraph 151 of the Complaint, but deny that Norplant was marketed under the same the regulatory standards applicable to Mirena® and deny that Mirena® and Norplant have the same mechanism of action and safety profile. Norplant ceased being marketed before the passage of the Physician Labeling Rule, which was designed to prevent potential overwarning.

152. Defendants admit the allegations in Paragraph 152 of the Complaint, but deny that Norplant was marketed under the same the regulatory standards applicable to Mirena® and deny that Mirena® and Norplant have the same mechanism of action and safety profile. Norplant ceased being marketed before the passage of the Physician Labeling Rule, which was designed to prevent potential overwarning.

153. Defendants admit the allegations in Paragraph 153 of the Complaint, but deny that Norplant was marketed under the same the regulatory standards applicable to Mirena® and deny that Mirena® and Norplant have the same mechanism of action and safety profile. Norplant ceased being marketed before the passage of the Physician Labeling Rule, which was designed to prevent potential overwarning.

154. Defendants admit the allegations in Paragraph 154 of the Complaint, but deny that Norplant was marketed under the same the regulatory requirements applicable to Mirena and deny that Mirena® and Norplant have the same mechanism of action and safety profile. Norplant ceased being marketed before the passage of the Physician Labeling Rule, which was designed to



prevent potential overwarning.

155. Defendants admit that the allegations in Paragraph 155 purport to selectively quote, paraphrase, and/or reference literature reports, which reports, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those reports, Defendants deny those allegations.

156. Defendants admit that the allegations in Paragraph 156 purport to selectively quote, paraphrase, and/or reference literature reports, which reports, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those reports, Defendants deny those allegations. Defendants further admit the allegations in Paragraph 156 of the Complaint that there were case reports of women and PTC/IIH using Norplant but deny that these spontaneous reports provide a reasonable evidence of a casual association between Mirena<sup>®</sup> and IIH. Defendants admit that by 2001 the Norplant label included an entry under the "Warnings" section for "Idiopathic Intracranial Hypertension" but deny that Mirena<sup>®</sup> and Norplant are substantially similar products; deny that the regulatory standards for labels for Mirena<sup>®</sup> and Norplant were the same at the time the Norplant label was amended; deny that there is reasonable scientific evidence of a causal relationship between Mirena<sup>®</sup> and PTC/IIH; and deny that there is reasonable scientific evidence of a causal relationship between LNG and PTC/IIH.

157. Defendants admit that the allegations in Paragraph 157 purport to selectively quote, paraphrase, and/or reference the label for Jadelle, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations. Defendants deny that Mirena<sup>®</sup> and Jadelle are substantially similar products; deny that there is a

reasonable scientific evidence of a causal relationship between Mirena<sup>®</sup> and PTC/IIH; and deny that there is reasonable scientific evidence of a causal relationship between LNG and PTC/IIH.

158. Defendants admit the allegations in Paragraph 158 of the Complaint but deny that Mirena<sup>®</sup> and Jadelle are substantially similar products; deny that there is a reasonable scientific evidence of a causal relationship between Mirena<sup>®</sup> and PTC/IIH; and deny that there is reasonable scientific evidence of a causal relationship between LNG and PTC/IIH.

159. Defendants admit the allegations in Paragraph 159 of the Complaint but deny that Mirena<sup>®</sup> and Jadelle are substantially similar products; deny that there is a reasonable scientific evidence of a causal relationship between Mirena<sup>®</sup> and PTC/IIH; and deny that there is reasonable scientific evidence of a causal relationship between LNG and PTC/IIH.

160. Defendants admit that the allegations in Paragraph 160 purport to selectively quote, paraphrase, and/or reference the label for Jadelle, which document, being in writing, speaks for itself. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations. Defendants deny that Mirena<sup>®</sup> and Jadelle are substantially similar products; deny that there is a reasonable scientific evidence of a causal relationship between Mirena<sup>®</sup> and PTC/IIH; and deny that there is reasonable scientific evidence of a causal relationship between LNG and PTC/IIH.

161. Defendants admit that the allegations in Paragraph 161 purport to selectively quote, paraphrase, and/or reference the labels for Jadelle and Norplant, which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of that document, Defendants deny those allegations. Defendants deny that Mirena<sup>®</sup> and Jadelle are substantially similar products; deny that Mirena<sup>®</sup> and Norplant are substantially similar products; deny that there is a reasonable

scientific evidence of a causal relationship between Mirena<sup>®</sup> and PTC/IIH; and deny that there is reasonable scientific evidence of a causal relationship between LNG and PTC/IIH.

162. Defendants admit that Norplant was withdrawn from the market in June of 2002, but Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 162 of the Complaint, and therefore, deny the same.

163. Defendants deny that there is “a wide body of information available to Defendants regarding the connection between levonorgestrel and PTC/IIH” as alleged in Paragraph 163 of the Complaint. Defendants admit that Mirena<sup>®</sup>’s FDA-approved label does not contain a warning regarding PTC/IIH but deny that there is reasonable scientific evidence of a causal relationship between Mirena<sup>®</sup> and PTC/IIH.

164. Defendants admit Mirena<sup>®</sup>’s FDA-approved label does not contain a warning regarding PTC/IIH as alleged in Paragraph 164 of the Complaint, but deny that there is reasonable scientific evidence of a causal relationship between Mirena<sup>®</sup> and PTC/IIH. Defendants are without knowledge or information sufficient to form a belief of the truth of the allegations in Paragraph 164 of the Complaint, and therefore, deny the same.

165. Defendants deny the allegations in Paragraph 165 of the Complaint.

166. The allegations contained in Paragraph 166 are denied as stated. Defendants admit that in December 2009, BHCP received a letter from the Department of Health and Human Services’ Division of Drug Marketing, Advertising, and Communications (“DDMAC”). Defendants further admits that the remaining allegations in Paragraph 166 purport to selectively quote, paraphrase, and/or reference the DDMAC letter, which document, being in writing, speaks for itself. To the extent Plaintiffs’ allegations are inconsistent with the actual language or content of the referenced document, Defendants deny those allegations.

167. The allegations contained in Paragraph 167 are denied as stated. Defendants admit that in December 2009, BHCP received a letter from DDMAC. Defendants further admit that the allegations in Paragraph 167 purport to selectively quote, paraphrase, and/or reference the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speak for themselves. To the extent Plaintiffs' allegations are inconsistent with the actual presentation made at the Simple Styles Program, Defendants deny those allegations.

168. The allegations contained in Paragraph 168 are denied as stated. Defendants admit that in December 2009, BHCP received a letter from DDMAC. Defendants further admit that the allegations in Paragraph 168 purport to selectively quote, paraphrase, and/or reference the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speak for themselves. To the extent Plaintiffs' allegations are inconsistent with the actual presentation made at the Simple Styles Program, Defendants deny those allegations.

169. The allegations contained in Paragraph 169 are denied as stated. Defendants admit that in December 2009, BHCP received a letter from DDMAC. Defendants further admit that the allegations in Paragraph 169 purport to selectively quote, paraphrase, and/or reference the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speak for themselves. To the extent Plaintiffs' allegations are inconsistent with the actual presentation made at the Simple Styles Program, Defendants deny those allegations.

170. The allegations contained in Paragraph 170 are denied as stated. Defendants admit that in December 2009, BHCP received a letter from DDMAC. Defendants further admit that the allegations in Paragraph 170 purport to selectively quote, paraphrase, and/or reference the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speak for themselves. To the extent Plaintiffs' allegations are inconsistent with the

actual presentation made at the Simple Styles Program, Defendants deny those allegations.

**FIRST RESPONSE TO “PLAINTIFF’S USE OF DEFENDANTS’ MIRENA AND  
RESULTING INJURY”**

171. Defendants admit the allegations in Paragraph 171 of the Complaint that each Plaintiff’s case involves facts specific to the individual Plaintiff, but deny that Defendants are liable to any individual Plaintiff

**FIRST RESPONSE TO “CAUSES OF ACTION”**

172. Paragraph 172 contains Plaintiffs’ characterization of their Consolidated Amended Complaint to which no response is required. To the extent a response is required, Defendants deny the same.

173. Defendants deny Plaintiffs are entitled to relief under any of the claims listed in Paragraph 173 (and its subparts).

174. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 174 of the Complaint.

175. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 175 of the Complaint.

176. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 176 of the Complaint.

177. Paragraph 177 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

**FIRST RESPONSE TO “COUNT I NEGLIGENCE”**

178. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the condition in which Plaintiff received the Mirena®, and therefore, deny the same. BHCP admits that, at certain times not specifically set forth in the

Complaint, it designed, developed, promoted, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 178, BHCP is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup>. Bayer Pharma AG further admits that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it manufactured Mirena<sup>®</sup>, and also denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 178, Bayer Pharma AG is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 178, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same.

179. Paragraph 179 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

180. Paragraph 180 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

181. Paragraph 181 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

182. Paragraph 182 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

183. Paragraph 183 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

184. Paragraph 184 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

185. Paragraph 185 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

186. Paragraph 186 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

187. Paragraph 187 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

188. Paragraph 188 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

189. Paragraph 189 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

190. Paragraph 190 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

191. Paragraph 191 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

192. Paragraph 192 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

193. Paragraph 193 contains legal conclusions to which no response is required. To

the extent a response is deemed necessary, Defendants deny.

194. Paragraph 194 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

195. Paragraph 195 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

196. Paragraph 196 (and its subparts) contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

197. Paragraph 197 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

198. Paragraph 198 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

199. Defendants deny the allegations in Paragraph 199 of the Complaint. Defendants also deny that there is a reasonable scientific evidence of a causal relationship between Mirena<sup>®</sup> and PTC/IIIH.

200. Paragraph 200 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

201. Paragraph 201 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants admit that the allegations in Paragraph 201 purport to selectively quote, paraphrase, and/or reference the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, Defendants deny those allegations. Defendants deny any additional allegations in Paragraph 201.



202. Paragraph 202 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

203. Paragraph 203 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

204. Paragraph 204 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

205. Paragraph 205 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants also deny that Plaintiff is entitled to the relief sought in Paragraph 205 of the Complaint.

206. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 206 of the Complaint.

**FIRST RESPONSE TO “COUNT II DESIGN DEFECT”**

207. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 206 of the Complaint.

208. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, promoted, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 208, BHCP is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup>. Bayer Pharma AG further admits that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it manufactured Mirena<sup>®</sup>, and also denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 208, Bayer Pharma AG is without knowledge or information sufficient to form a

belief as to the truth of those, and therefore, denies the same. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 208, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same.

209. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the condition in which Plaintiff received the Mirena<sup>®</sup>, and therefore, deny the same. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, promoted, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 209, BHCP is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup>. Bayer Pharma AG further admits that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it manufactured Mirena<sup>®</sup>, and also denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 209, Bayer Pharma AG is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008,

Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 209, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same.

210. Paragraph 210 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

211. Paragraph 211 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

212. Paragraph 212 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

213. Paragraph 213 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

214. Paragraph 214 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

215. Paragraph 215 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

216. Paragraph 216 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

217. Paragraph 217 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

218. Paragraph 218 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

219. Paragraph 219 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

220. Paragraph 220 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

221. Paragraph 221 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

222. Paragraph 222 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

223. Paragraph 223 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

224. Paragraph 224 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

225. Paragraph 225 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

226. Paragraph 226 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

227. Paragraph 227 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants also deny that Plaintiff is entitled to the relief sought in Paragraph 227 of the Complaint.

228. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 228 of the Complaint.

**FIRST RESPONSE TO “COUNT III FAILURE TO WARN”**

229. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 228 of the Complaint.

230. Paragraph 230 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, promoted, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 230, BHCP is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup>. Bayer Pharma AG further admits that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it manufactured Mirena<sup>®</sup>, and also denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 230, Bayer Pharma AG is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 230, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those, and therefore denies the same.

231. Paragraph 231 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

232. Paragraph 232 contains legal conclusions to which no response is required. To

the extent a response is deemed necessary, Defendants deny.

233. Paragraph 233 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

234. Paragraph 234 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

235. Paragraph 235 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

236. Defendants deny the allegations in Paragraph 236 of the Complaint.

237. Paragraph 237 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

238. Paragraph 238 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

239. Paragraph 239 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

240. Paragraph 240 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

241. Paragraph 241 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

242. Defendants deny the allegations in Paragraph 242 of the Complaint.

243. Defendants deny the allegations in Paragraph 243 of the Complaint.

244. Paragraph 244 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

245. Defendants deny the allegations in Paragraph 245 of the Complaint.

246. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 246 of the Complaint, and therefore, deny the same.

247. Paragraph 247 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

248. Paragraph 248 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

249. Paragraph 249 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation that “Plaintiff did not have the same knowledge as Defendants,” and therefore deny the same.

250. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 250 of the Complaint, and therefore, deny the same.

251. Paragraph 251 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

252. Paragraph 252 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

253. Paragraph 253 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants also deny Plaintiff is entitled to the relief sought in Paragraph 253 of the Complaint.

254. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 254 of the Complaint.

**FIRST RESPONSE TO “COUNT IV STRICT LIABILITY”**

255. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 254 of the Complaint.

256. Paragraph 256 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

257. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore, deny the same. BHCP admits that, at certain times not specifically set forth in the Complaint, it developed, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 257, BHCP is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup>. Bayer Pharma AG further admits that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it manufactured Mirena<sup>®</sup>, and also denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 257, Bayer Pharma AG is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 257, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Paragraph 257 also contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.



258. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 258 of the Complaint, and therefore, deny the same.

259. Paragraph 259 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

260. Paragraph 260 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

261. Paragraph 261 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

262. Paragraph 262 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

263. Paragraph 263 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

264. Paragraph 264 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

265. Paragraph 265 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

266. Paragraph 266 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

267. Paragraph 267 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

268. Paragraph 268 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

269. Paragraph 269 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

270. Paragraph 270 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

271. Paragraph 271 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

272. Paragraph 272 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

273. Paragraph 273 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

274. Defendants deny the allegations in Paragraph 274 of the Complaint.

275. Paragraph 275 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

276. Paragraph 276 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

277. Paragraph 277 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

278. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 278 of the Complaint, and therefore, deny the same.

279. Paragraph 279 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

280. Paragraph 280 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

281. Paragraph 281 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

282. Paragraph 282 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

283. Paragraph 283 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

284. Paragraph 284 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

285. Paragraph 285 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants also deny that Plaintiff is entitled to the relief sought in Paragraph 285 of the Complaint.

286. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 286 of the Complaint.

**FIRST RESPONSE TO “COUNT V BREACH OF IMPLIED WARRANTY”**

287. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 286 of the Complaint.

288. BHCP admits that, at certain times not specifically set forth in the Complaint, it developed, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 288, BHCP is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup>. Bayer Pharma AG further admits that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it manufactured Mirena<sup>®</sup>, and also denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the

vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 288, Bayer Pharma AG is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 288, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same.

289. Paragraph 289 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

290. Paragraph 290 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

291. Paragraph 291 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 291 of the Complaint, and therefore, deny the same.

292. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 292 of the Complaint, and therefore, deny the same.

293. Paragraph 293 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

294. Paragraph 294 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

295. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 295 of the Complaint, and therefore, deny the same.

296. Paragraph 296 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 296 of the Complaint, and therefore, deny the same.

297. Paragraph 297 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants also deny that Plaintiff is entitled to the relief sought in Paragraph 297 of the Complaint.

298. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 298 of the Complaint.

**FIRST RESPONSE TO “COUNT VI BREACH OF EXPRESS WARRANTY”**

299. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 298 of the Complaint.

300. Paragraph 300 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. BHCP admits that, at certain times not specifically set forth in the Complaint, it developed, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 300, BHCP is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Pharma AG admits that, at certain times not specified in the Complaint, it developed Mirena<sup>®</sup>. Bayer Pharma AG further admits that, from September 1, 2008, it sold Mirena<sup>®</sup> to BHCP. Bayer Pharma AG denies that it

manufactured Mirena<sup>®</sup>, and also denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 300, Bayer Pharma AG is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same. Bayer Oy admits that, at certain times not specified in the Complaint, it developed and manufactured Mirena<sup>®</sup>. Bayer Oy further admits that it sold Mirena<sup>®</sup> to BHCP until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena<sup>®</sup> to Bayer Pharma AG, which sold some of the product to BHCP. Bayer Oy denies that it marketed, sold or distributed Mirena<sup>®</sup> to patients or consumers in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 300, Bayer Oy is without knowledge or information sufficient to form a belief as to the truth of those, and therefore, denies the same.

301. Paragraph 301 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

302. Paragraph 302 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

303. Paragraph 303 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

304. Paragraph 304 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

305. Paragraph 305 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

306. Defendants deny the allegations in Paragraph 306 of the Complaint.

307. Paragraph 307 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

308. Paragraph 308 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 308 of the Complaint, and therefore, deny the same.

309. Paragraph 309 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 309 of the Complaint, and therefore, deny the same.

310. Paragraph 310 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

311. Paragraph 311 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants deny that Plaintiff is entitled to the relief sought in Paragraph 311 of the Complaint.

312. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 312 of the Complaint.

**FIRST RESPONSE TO “COUNT VII NEGLIGENT MISREPRESENTATION”**

313. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 312 of the Complaint.

314. Paragraph 314 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

315. Paragraph 315 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

316. Paragraph 316 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

317. Paragraph 317 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

318. Paragraph 318 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

319. Paragraph 319 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

320. Paragraph 320 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

321. Paragraph 321 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

322. Paragraph 322 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

323. Paragraph 323 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

324. Paragraph 324 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

325. Paragraph 325 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

326. Paragraph 326 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.



327. Paragraph 327 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

328. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 328 of the Complaint, and therefore, deny the same.

329. Paragraph 329 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

330. Paragraph 330 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

331. Paragraph 331 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

332. Paragraph 332 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 332 of the Complaint, and therefore, deny the same.

333. Paragraph 333 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

334. Paragraph 334 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

335. Paragraph 335 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

336. Paragraph 336 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

337. Paragraph 337 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

338. Paragraph 338 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

339. Paragraph 339 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

340. Paragraph 340 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

341. Paragraph 341 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

342. Paragraph 342 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

343. Paragraph 343 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

344. Defendants admit that the allegations in Paragraph 344 purport to selectively quote, paraphrase, and/or reference marketing materials, the FDA-approved Physician Prescribing Information for Mirena<sup>®</sup>, and the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

345. Paragraph 345 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

346. Paragraph 346 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

347. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 347 of the Complaint, and therefore, deny the same.

348. Paragraph 348 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants deny that Plaintiff is entitled to the relief sought in Paragraph 348 of the Complaint.

349. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 349 of the Complaint.

**FIRST RESPONSE TO “COUNT VIII FRAUDULENT MISREPRESENTATION”**

350. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 349 of the Complaint.

351. Paragraph 351 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

352. Paragraph 352 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

353. Paragraph 353 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

354. Paragraph 354 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

355. Paragraph 355 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

356. Paragraph 356 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

357. Paragraph 357 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

358. Paragraph 358 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

359. Defendants admit that the allegations in Paragraph 359 purport to selectively quote, paraphrase, and/or reference advertising materials, marketing materials, and the FDA-approved Patient Information Booklet for Mirena<sup>®</sup>, which documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

360. Paragraph 360 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

361. Paragraph 361 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

362. Paragraph 362 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 362 of the Complaint, and therefore, deny the same.

363. Paragraph 363 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

364. Paragraph 364 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

365. Paragraph 365 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

366. Paragraph 366 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

367. Paragraph 367 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 367 of the Complaint, and therefore, deny the same.

368. Paragraph 368 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

369. Paragraph 369 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

370. Paragraph 370 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

371. Paragraph 371 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

372. Paragraph 372 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

373. Defendants deny the allegations in Paragraph 373 of the Complaint.

374. Paragraph 374 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

375. Defendants admit that the allegations in Paragraph 375 purport to selectively quote, paraphrase, and/or reference marketing materials, the FDA-approved Physician Prescribing Information for Mirena®, and the FDA-approved Patient Information Booklet for Mirena®, which documents, being in writing, speak for themselves. To the extent that Plaintiffs'

allegations are inconsistent with, or take out of context, the actual language or content of those documents, Defendants deny those allegations.

376. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 376 of the Complaint, and therefore, deny the same.

377. Paragraph 377 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

378. Paragraph 378 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

379. Paragraph 379 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

380. Paragraph 380 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

381. Paragraph 381 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

382. Paragraph 382 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

383. Paragraph 383 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

384. Paragraph 384 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

385. Defendants deny the allegations in Paragraph 385 of the Complaint.

386. Paragraph 386 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

387. Paragraph 387 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

388. Paragraph 388 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

389. Paragraph 389 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 389 of the Complaint, and therefore, deny the same.

390. Paragraph 390 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 390 of the Complaint, and therefore, deny the same.

391. Paragraph 391 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

392. Paragraph 392 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants deny that Plaintiff is entitled to the relief sought in Paragraph 392 of the Complaint.

393. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 393 of the Complaint.

**FIRST RESPONSE TO“COUNT IX FRAUD”**

394. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 393 of the Complaint.

395. Paragraph 395 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

396. Paragraph 396 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

397. Paragraph 397 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

398. Paragraph 398 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

399. Paragraph 399 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

400. Paragraph 400 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

401. Paragraph 401 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

402. Paragraph 402 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

403. Paragraph 403 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

404. Paragraph 404 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

405. Paragraph 405 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

406. Paragraph 406 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

407. Paragraph 407 contains legal conclusions to which no response is required. To



the extent a response is deemed necessary, Defendants deny.

408. Paragraph 408 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

409. Paragraph 409 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

410. Paragraph 410 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

411. Paragraph 411 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

412. Paragraph 412 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

413. Paragraph 413 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

414. Paragraph 414 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

415. Paragraph 415 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

416. Paragraph 416 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

417. Paragraph 417 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 417 of the Complaint, and therefore, deny the same.

418. Paragraph 418 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

419. Paragraph 419 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

420. Paragraph 420 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

421. Paragraph 421 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

422. Paragraph 422 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

423. Paragraph 423 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

424. Paragraph 424 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

425. Paragraph 425 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

426. Paragraph 426 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

427. Paragraph 427 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

428. Paragraph 428 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

429. Paragraph 429 contains legal conclusions to which no response is required. To

the extent a response is deemed necessary, Defendants deny. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 429 of the Complaint.

430. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 430 of the Complaint.

**FIRST RESPONSE TO “COUNT X STATE CONSUMER FRAUD VIOLATIONS”**

431. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 430 of the Complaint.

432. Paragraph 432 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 432 of the Complaint.

433. Paragraph 433 contains Plaintiffs’ description of possible future pleadings to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 433 of the Complaint.

434. Paragraph 434 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

435. Paragraph 435 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

436. Paragraph 436 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

437. Paragraph 437 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

438. Paragraph 438 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

439. Paragraph 439 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

440. Paragraph 440 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

441. Paragraph 441 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

442. Paragraph 442 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

443. Paragraph 443 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

444. Paragraph 444 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

445. Paragraph 445 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

446. Paragraph 446 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

447. Paragraph 447 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

448. Paragraph 448 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

449. Paragraph 449 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

450. Paragraph 450 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

451. Paragraph 451 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

452. Paragraph 452 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

453. Paragraph 453 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

454. Paragraph 454 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

455. Paragraph 455 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

456. Paragraph 456 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

457. Paragraph 457 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

458. Paragraph 458 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

459. Paragraph 459 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

460. Paragraph 460 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

461. Paragraph 461 contains legal conclusions to which no response is required. To

the extent a response is deemed necessary, Defendants deny.

462. Paragraph 462 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

463. Paragraph 463 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

464. Paragraph 464 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

465. Paragraph 465 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

466. Paragraph 466 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

467. Paragraph 467 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

468. Paragraph 468 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

469. Paragraph 469 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

470. Paragraph 470 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

471. Paragraph 471 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

472. Paragraph 472 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

473. Paragraph 473 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

474. Paragraph 474 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

475. Paragraph 475 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

476. Paragraph 476 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

477. Paragraph 477 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

478. Paragraph 478 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

479. Paragraph 479 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

480. Paragraph 480 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

481. Paragraph 481 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

482. Paragraph 482 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

483. Paragraph 483 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny. Defendants are also without knowledge or information sufficient to form a belief as to the truth of the allegations in

Paragraph 483 of the Complaint, and therefore, deny the same.

484. Paragraph 484 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

**FIRST RESPONSE TO “REQUEST FOR PUNITIVE DAMAGES”**

485. This paragraph requires no response, and Defendants incorporate herein all of their responses to Paragraphs 1 through 484 of the Complaint.

486. Defendants deny the allegations in Paragraph 486 (and its subparts) of the Complaint.

487. Paragraph 487 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

488. Paragraph 488 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

489. Paragraph 489 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

490. Paragraph 490 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendants deny.

491. Defendants deny Plaintiff is entitled to the relief sought in Paragraph 491. Defendants also deny Plaintiff is entitled to the relief sought in the unnumbered “Wherefore” paragraph (and its subparts) immediately following Paragraph 491.

**AFFIRMATIVE/SEPARATE DEFENSES**

492. Discovery and investigation may reveal that one or more of the following additional defenses should be available to Defendants. Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy accordingly reserve the right to assert these separate and



additional defenses. Upon completion of discovery, if the facts warrant, Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy may withdraw any of these additional defenses as may be appropriate. Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy further reserve the right to amend their Answer and defenses to assert additional defenses and other claims, as discovery proceeds. Further answering, and by way of additional defense, Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy state as follows:

**FIRST SEPARATE DEFENSE TO ALL COUNTS**

493. Plaintiffs' Complaint and each and every count contained therein fails to state a cause of action or claim on which relief can be granted.

**SECOND SEPARATE DEFENSE TO ALL COUNTS**

494. Plaintiffs are improperly joined in this action.

**THIRD SEPARATE DEFENSE TO ALL COUNTS**

495. Defendants preserve lack of service of process or insufficiency of service of process to the extent Defendants have not been served properly under the Federal Rules of Civil Procedure or any agreed orders regarding service entered by the Court.

**FOURTH SEPARATE DEFENSE TO ALL COUNTS**

496. The Court is an improper venue for the trial of this action.

**FIFTH SEPARATE DEFENSE TO ALL COUNTS**

497. The Court is not the proper forum for the trial of this action and is an inconvenient forum for the just adjudication of Plaintiffs' claims.

**SIXTH SEPARATE DEFENSE TO ALL COUNTS**

498. The acts and omissions of Plaintiffs caused and/or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrines of contributory negligence and/or comparative negligence. Plaintiffs' recovery, if any, therefore is barred or should be apportioned in accordance with applicable law.

**SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

499. Plaintiffs' Complaint fails to state a claim to the extent Defendants did not manufacture or distribute the product allegedly used by a particular Plaintiff.

**EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

494. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or statutes of repose.

**NINTH SEPARATE DEFENSE TO ALL COUNTS**

495. Plaintiffs' claims are barred in whole or in part by laches, waiver, and/or estoppel.

**TENTH SEPARATE DEFENSE TO ALL COUNTS**

496. Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

**ELEVENTH SEPARATE DEFENSE TO ALL COUNTS**

497. To the extent applicable to the facts and circumstances of this case, Plaintiffs are not real parties in interest and lack capacity and/or standing to bring the claims asserted in the Complaint.

**TWELFTH SEPARATE DEFENSE TO ALL COUNTS**

498. If Plaintiffs suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly

assumed by Plaintiffs. Plaintiffs' recovery accordingly is barred or should be reduced by Plaintiffs' assumption of the risk.

**THIRTEENTH SEPARATE DEFENSE TO ALL COUNTS**

499. Plaintiffs' Complaint fails to state a claim for fraud, misrepresentation, deceit, concealment, suppression and/or omission, and fails to allege the circumstances constituting fraud with the required particularity.

**FOURTEENTH SEPARATE DEFENSE TO ALL COUNTS**

500. The alleged damages and injuries, if any, were the result of unavoidable circumstances that could not have been prevented by any person or entity, including Defendants.

**FIFTEENTH SEPARATE DEFENSE TO ALL COUNTS**

501. Plaintiffs did not suffer any actual injury, loss, or damages because of the alleged use of Mirena<sup>®</sup>.

**SIXTEENTH SEPARATE DEFENSE TO ALL COUNTS**

502. The injuries and damages sustained by Plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and no act or omission on the part of Defendants was a proximate or competent producing cause of such alleged injuries or damages.

**SEVENTEENTH SEPARATE DEFENSE TO ALL COUNTS**

503. The injuries and damages sustained by Plaintiffs, if any, were caused, in whole or in part, by pre-existing or subsequent physical, medical, and/or physiological conditions, for which Defendants had no legal responsibility.

**EIGHTEENTH SEPARATE DEFENSE TO ALL COUNTS**

504. The acts and omissions of Plaintiffs and/or other persons or entities, over whom Defendants had no supervision or control and for whose actions and omissions Defendants had

no legal responsibility, caused or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrine of comparative negligence. Plaintiffs' recovery, if any, therefore is barred or should be reduced and/or apportioned in accordance with applicable law.

**NINETEENTH SEPARATE DEFENSE TO ALL COUNTS**

505. Plaintiffs' claims are barred as a matter of law pursuant to the relevant provision of Restatement (Third) of Torts, including, but not limited to, the Restatement (Third) of Torts: Product Liability, § 6, comment f, and the Restatement (Second) of Torts, including, but not limited to, § 402A, comment k.

**TWENTIETH SEPARATE DEFENSE TO ALL COUNTS**

506. To the extent applicable to Plaintiffs' claims, Defendants will rely upon the rights, defenses, and presumptions accorded to them under the applicable states' products liability law.

**TWENTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

507. Plaintiffs' claims are or may be barred, in whole or in part, by the applicable states' products liability law.

**TWENTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

508. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part from collateral sources. To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under the applicable states' laws.

**TWENTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

509. Plaintiffs' claims are barred because Mirena<sup>®</sup> was neither defective nor unreasonably dangerous in its design, manufacture, or marketing, was reasonably safe and reasonably fit for its intended use, and was properly prepared in accordance with the applicable standard of care. The warnings and instructions accompanying Mirena<sup>®</sup> at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate warnings and instructions.

**TWENTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

510. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

**TWENTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

511. Plaintiffs' causes of action are or may be barred in whole or in part by Plaintiffs' failure to assert a safer design for Mirena<sup>®</sup>.

**TWENTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

512. To the extent applicable under governing law, Plaintiffs' claims are barred in whole or in part by the learned intermediary doctrine.

**TWENTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

513. Defendants did not sell or distribute Mirena<sup>®</sup> to Plaintiffs, and Plaintiffs did not receive or rely on any representations or warranties as alleged in the Complaint. Plaintiffs' claims for breach of warranty are barred by lack of privity between Plaintiffs on one hand and Defendants on the other.

**TWENTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

514. Plaintiffs did not detrimentally rely on any labeling, warnings, or information concerning Mirena<sup>®</sup>.

**TWENTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

515. Plaintiffs' prescribing physicians did not rely on any representations by Defendants in treating Plaintiffs, or in states where the learned intermediary doctrine does not apply, Plaintiffs did not rely on any representations by Defendants.

**THIRTIETH SEPARATE DEFENSE TO ALL COUNTS**

516. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, to the extent that Plaintiffs seek recovery for any alleged breach of a post-sale duty to warn, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

**THIRTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

517. Plaintiffs' claims for breach of warranty are barred because Plaintiffs failed to give timely notice of any alleged breach of warranty.

**THIRTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

518. Plaintiffs' claims of breach of warranty are barred by the applicable provisions of the applicable states' laws.

**THIRTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

519. Defendants did not make any representations of fact or warranties material to Plaintiffs' treatment with Mirena<sup>®</sup>. Any opinions or commendations expressed by Defendants are not actionable as representations or warranties.

**THIRTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

520. Plaintiffs' Complaint fails to state a claim upon which relief can be granted against Defendants in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of the prescription contraceptive system Mirena<sup>®</sup>, including

adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the product was designed, manufactured, marketed and sold in a reasonable and prudent manner based upon available medical and scientific knowledge.

**THIRTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

521. The methods, standards, and techniques utilized with respect to the design, manufacture, marketing, and sale of Mirena<sup>®</sup>, including but not limited to adequate warnings and instructions with respect to the product's use included in the product's package inserts and other literature, conformed to the applicable state of the art. Such conformity creates a rebuttable presumption that Mirena<sup>®</sup> was not defective and that there was no negligence.

**THIRTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

522. Mirena<sup>®</sup> complied with the applicable product safety regulations promulgated by the United States Food and Drug Administration. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, distribution, marketing, and sale of Mirena<sup>®</sup>, and that it was neither defective nor unreasonably dangerous. Plaintiffs' recovery is accordingly barred.

**THIRTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

523. If Plaintiffs sustained the injuries or incurred the expenses as alleged in the Complaint, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of Mirena<sup>®</sup>. Plaintiffs' recovery accordingly is barred.

**THIRTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

524. Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal government's regulation of the manufacturing, testing, marketing, sale and labeling of prescription drugs.

**THIRTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

525. To the extent Plaintiffs' claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

**FORTIETH SEPARATE DEFENSE TO ALL COUNTS**

526. Plaintiffs' claims regarding warnings and labeling are barred by the doctrine of primary jurisdiction, in that the United States Food and Drug Administration is charged under law with determining the content of warnings and labeling for prescription drugs.

**FORTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

527. Plaintiffs cannot state a claim with regard to the warnings and labeling for prescription drugs because the remedy sought by Plaintiffs is subject to the exclusive regulation of the United States Food and Drug Administration.

**FORTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

528. This Court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the United States Food and Drug Administration.



**FORTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

529. Any claims by Plaintiffs relating to alleged communications with governmental regulatory agencies are barred in whole or in part under applicable law, including the First and Fourteenth Amendment rights to petition the government.

**FORTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

530. Plaintiffs' claims are barred in whole or in part because the commercial speech relating to Mirena® was not false or misleading and is protected under the First and Fourteenth Amendments to the United States Constitution and applicable state constitutional provisions.

**FORTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

531. Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate their alleged damages.

**FORTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

532. Plaintiffs' claims are barred because any injuries or damages sustained by Plaintiffs were directly and proximately caused by the failure of the learned intermediary and/or Plaintiffs to heed warnings and instructions.

**FORTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

533. Plaintiffs' claims purportedly asserted under statutes and regulations relating to prescription drugs fail, in whole or in part, because those statutes and regulations do not contain or create any private cause of action.

**FORTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

534. Plaintiffs' claims for breach of warranty, express or implied, are barred by the applicable states' Uniform Commercial Code or other applicable law.

**FORTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

535. Plaintiffs fail to state a claim for express warranty because there was no affirmation of fact or promise made by Defendants relating to the product that was the basis of the bargain.

**FIFTIETH SEPARATE DEFENSE TO ALL COUNTS**

536. To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Defendants, if any, should be reduced accordingly. Pursuant to the common law right to credits, reductions and setoffs, and other applicable law, any settlement reached between Plaintiffs and a named defendant in this action shall reduce the amount of Plaintiffs' recovery by the stipulated amount of the agreement, or in the amount of consideration paid, whichever is greater.

**FIFTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

537. Plaintiffs' Complaint fails to state a claim on which relief can be granted as to costs and disbursements, attorney fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, unjust enrichment, disgorgement, restitution, or treble damages.

**FIFTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

538. Plaintiffs' claims for costs, fees, and/or interest are barred and/or limited for failure to comply with the requirements of the applicable states' laws.

**FIFTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

539. Any claim for prejudgment interest is barred by Plaintiffs' failure to make a demand for payment or offer of settlement in writing, failure to send the demand or offer by certified mail, and failure to leave the demand or offer open for the requisite number of days under the applicable law.

**FIFTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

540. Plaintiffs' Complaint fails to state a claim against Defendants on which relief can be granted for punitive or exemplary damages.

**FIFTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

541. Defendants deny any conduct for which punitive or exemplary damages could or should be awarded and denies that Plaintiffs have produced evidence sufficient to support or sustain the imposition of punitive damages against Defendants pursuant to the applicable standards of proof.

**FIFTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

542. Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague and/or overbroad, would violate Defendant's constitutional rights as secured by the Fifth, Seventh, and Fourteenth Amendments to the United States Constitution, and would contravene the prohibition of excessive fines and other provisions of the United States Constitution and the applicable state constitution.

**FIFTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

543. Plaintiffs cannot recover punitive or exemplary damages against Defendants because such an award, which is penal in nature, would violate Defendants' rights under the United States Constitution and the applicable state constitution, unless Defendants are afforded the same procedural safeguards as are criminal defendants.

**FIFTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

544. Any imposition of punitive or exemplary damages in this case against Defendants would contravene the Commerce Clause of the United States Constitution, in that such an award would constitute an undue and unreasonable burden on interstate commerce.

**FIFTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

545. With respect to Plaintiffs' demand for punitive or exemplary damages, Defendants incorporate by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under the applicable state law.

**SIXTIETH SEPARATE DEFENSE TO ALL COUNTS**

546. No act or omission of Defendants was intentional, fraudulent, malicious, reckless, in any way morally culpable, or made with conscious, malicious, or intentional disregard for the health and well-being of Plaintiffs or others. Defendants assert all statutory or judicial protections from punitive or exemplary damages that are available under applicable law, and any award of punitive or exemplary damages is barred.

**SIXTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

547. Plaintiffs' claim for punitive damages against Defendants cannot be sustained because, in all respects pertinent to this action, Defendants complied with applicable industry standards and did not engage in a deliberate course of conduct which knowingly endangered those using Mirena®.

**SIXTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

548. Plaintiffs' claim for punitive damages against Defendants cannot be sustained to the extent that, prior to the entry of any judgment or award in this case, an award of punitive or exemplary damages has been recovered from Defendants in a court of this state relating to Mirena®.

**SIXTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

549. Plaintiffs' Complaint seeks damages in excess of those permitted by law. Defendants assert any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

**SIXTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

550. Plaintiffs' claims of injury and claims for damages are speculative.

**SIXTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

551. Plaintiffs' Complaint fails to state a claim on which relief can be granted for joint and several liability.

**SIXTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

552. Plaintiffs' recovery, if any, against Defendants is subject to the applicable states' several or joint and several law.

**SIXTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

553. Plaintiffs' recovery, if any, is subject to the applicable states' limitations on damages.

**SIXTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

554. Plaintiffs' claims for recovery are limited by any applicable states' statutory and common law limitations on awards, caps on recovery, and set-offs.

**SIXTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

555. To the extent that Defendants are found jointly and severally liable, which is expressly denied, Defendants are entitled to contribution from other defendants and/or relies upon applicable states' laws regarding contribution among tortfeasors.

**SEVENTIETH SEPARATE DEFENSE TO ALL COUNTS**

556. The Court lacks personal jurisdiction over Defendants with respect to Plaintiffs' claims. Defendants preserve all defenses relating to personal jurisdiction and venue.

**SEVENTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

557. Defendants adopt and incorporate by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Defendants' defenses pleaded in this Answer.

**SEVENTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

558. Defendants have disclaimed any alleged express or implied warranties.

**SEVENTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

559. Defendants reserve the right to move to bifurcate those punitive damage issues provided for by applicable law.

**SEVENTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

560. To the extent that any party or non-party is found to have fault for Plaintiffs' alleged injuries, Plaintiffs' damages should be apportioned in accordance with the comparative fault of all parties at fault.

**SEVENTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

561. Plaintiffs' claims of product defect, if any, are or may be barred by Section 4 of the Restatement (Third) of Torts: Products Liability, because Mirena<sup>®</sup> complied with applicable product safety statutes and administrative regulations.

**SEVENTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

562. Plaintiffs' claims are barred by Sections 6(c) and (d) of the Restatement (Third) of Torts: Products Liability. Reasonable physicians knowing of the reasonably foreseeable risks and

therapeutic benefits associated with Mirena<sup>®</sup> would have prescribed and did prescribe the drug for classes of patients. In addition, reasonable instructions or warnings were provided to prescribing physicians.

**SEVENTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

563. Plaintiffs' claims are barred because the benefits of Mirena<sup>®</sup> outweigh the risks, if any, that might be associated with the product.

**SEVENTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

564. Plaintiffs' alleged injuries and damages, if any, were the result of an idiosyncratic or allergic reaction, which Defendants could not reasonably foresee and over which Defendants had and have no control.

**SEVENTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

565. Any award of punitive or exemplary damages against Defendants is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996); *State Farm Mutual Automobile Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007); and *Exxon Shipping Co. v. Baker*, 554 U.S. 471 (2008).

**EIGHTIETH SEPARATE DEFENSE TO ALL COUNTS**

566. Whatever damages may have been sustained at the time and place alleged in Plaintiffs' Complaint was caused, in whole or in part, by the culpable conduct of Plaintiffs and without any negligence on the part of Defendants. Damages, if any, are to be diminished proportionally to the culpable conduct of Plaintiffs.

**EIGHTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

567. Plaintiffs' claims may be barred, in whole or in part, by the doctrines of merger,

bar, *res judicata*, collateral estoppel, release, discharge, and accord and satisfaction.

**EIGHTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

568. Defendants give notice that to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, Defendants intend to rely upon same in defense of this action.

**EIGHTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

569. Defendants deny, to the extent the actions alleged may have occurred, that any other entity engaging in the activities alleged was acting as the agent or servant of Defendants, or at the instruction or subject to the control of Defendants with regard to any of the actions described in the Complaint; thus, Defendants are not liable for any acts or omissions of such third parties as a matter of law.

**EIGHTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

570. Plaintiffs' claims are barred because a reasonable purchaser and/or consumer would have been aware of the alleged risks of Mirena<sup>®</sup> or because Plaintiffs knew of the alleged risks of Mirena<sup>®</sup>.

**EIGHTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

571. Plaintiffs' causes of action are barred, in whole or in part, by the failure to assert a reasonable safer alternative design for Mirena<sup>®</sup>.

**EIGHTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

572. Plaintiffs are barred from recovering any damages to the extent that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by Plaintiffs without substantially impairing the usefulness or intended purpose of Mirena<sup>®</sup>.



**EIGHTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

573. The claims asserted in the Complaint under any applicable “consumer fraud” laws are insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

**EIGHTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

574. The claims asserted in the Complaint under any applicable “consumer fraud” laws are barred, in whole or in part, because the applicable “consumer fraud” laws unconstitutionally burden interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

**EIGHTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

575. Insofar as any applicable “consumer fraud” laws require exhaustion of administrative or other remedies, the claims asserted in the Complaint under applicable “consumer fraud” laws should be stayed or dismissed because, on information and belief, Plaintiffs have not exhausted those administrative or other remedies.

**NINETIETH SEPARATE DEFENSE TO ALL COUNTS**

576. Plaintiffs’ Complaint fails to properly plead Plaintiffs’ claims under any applicable “consumer fraud” laws with sufficient particularity.

**NINETY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

577. The claims asserted in the Complaint under applicable “consumer fraud” laws are barred because the Complaint does not allege proximate causation for Plaintiffs’ alleged injuries.

**NINETY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

578. The claims asserted in the Complaint under any applicable “consumer fraud” laws

are barred to the extent reliance is required.

**NINETY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

579. The claims asserted in the Complaint under any applicable “consumer fraud” laws are barred to the extent that knowledge or intent to deceive is required.

**NINETY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

580. The claims asserted in the Complaint under any applicable “consumer fraud” laws are barred to the extent that notice required.

**NINETY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

581. The claims asserted in the Complaint under any applicable “consumer fraud” laws are barred to the extent that Plaintiffs must have suffered an “ascertainable loss,” i.e., an actual loss that is susceptible to reasonably precise calculation.

**NINETY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

582. The claims asserted in the Complaint under any applicable “consumer fraud” laws are barred to the extent that “actual damages” are required.

**NINETY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

583. The claims asserted in the Complaint under any applicable “consumer fraud” laws are barred to the extent that no private right of action is available.

**NINETY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

584. The claims asserted in the Complaint under any applicable “consumer fraud” laws are barred to the extent that under such laws claims can be brought only with respect to transactions or conduct that occurred exclusively or primarily within the state and the transactions and conduct at issue occurred outside of the state.

**NINETY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

585. A prescription pharmaceutical is not a consumer product or transaction, or is otherwise not the type of product or transaction covered by the applicable state consumer protection and trade practices law, or consumer fraud laws.

**ONE HUNDREDTH SEPARATE DEFENSE TO ALL COUNTS**

586. Plaintiffs' Complaint fails to state a claim under any applicable states' consumer protection law, consumer fraud law, and trade practices law.

**ONE HUNDRED FIRST SEPARATE DEFENSE TO ALL COUNTS**

587. Defendants assert any other rights or defenses accorded them under any applicable states' consumer protection law and trade practices law.

**ONE HUNDRED SECOND SEPARATE DEFENSE TO ALL COUNTS**

588. Plaintiffs' right to recover damages in this action, if any, may be statutorily limited by the applicable states' wrongful death and/or survival law.

**ONE HUNDRED THIRD SEPARATE DEFENSE TO ALL COUNTS**

589. Defendants assert any other procedural and substantive defenses available under the applicable states' wrongful death and survival law.

**ONE HUNDRED FOURTH SEPARATE DEFENSE TO ALL COUNTS**

590. Plaintiffs' claims for consortium-related damages are barred to the extent that any other claim contained in Plaintiffs' Complaint is or may be barred.

**ONE HUNDRED FIFTH SEPARATE DEFENSE TO ALL COUNTS**

591. If Plaintiffs have filed bankruptcy during the relevant time period of the events alleged in the Complaint or file for bankruptcy at some point in the future, the claims of Plaintiffs may be "property of the bankruptcy estate," which should be prosecuted by the

bankruptcy trustee rather than Plaintiffs, or, if not disclosed by Plaintiffs on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

**ONE HUNDRED SIXTH SEPARATE DEFENSE TO ALL COUNTS**

592. Plaintiffs' actions should be dismissed to the extent Plaintiffs have asserted the same claims in actions pending in other jurisdictions.

**ONE HUNDRED SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

593. Defendants adopt all defenses available under the law that governs the action.

**ONE HUNDRED EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

594. Plaintiffs' alleged reliance, if any, on alleged misrepresentations, omissions or concealment by Defendants, which is categorically denied, was not reasonable and did not cause any of the damages alleged by Plaintiffs.

**ONE HUNDRED NINTH SEPARATE DEFENSE TO ALL COUNTS**

595. Plaintiffs' causes of action for products liability are barred because the relevant product was consistent with or exceeded consumer expectations.

**ONE HUNDRED TENTH SEPARATE DEFENSE TO ALL COUNTS**

596. Defendants reserve the right to amend its answer and separate and affirmative defenses to conform to such facts as may be revealed in discovery or otherwise.

**DEMAND FOR JURY TRIAL**

597. Defendants specifically request and demand a trial by jury on all facts and issues in this action, made up of the maximum allowable number of jurors.

**WHEREFORE**, Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy deny any and all liability with regard to Plaintiffs' claims, and respectfully requests that Plaintiffs' claims against it be dismissed with prejudice and that Bayer HealthCare

Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy be awarded such general, further relief as justice may require.

Dated: August 14, 2017

Respectfully submitted,

/s/ James Shepherd

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing was filed via the ECF/CM system with the Clerk of the Court, which will have sent notice to all attorneys of record in this matter on this 14th day of August, 2017.

/s/ James Shepherd

James Shepherd